89-1879

No. _____

IN THE

Supreme Court of the United States

October Term, 1989

MICHAEL J. FRIEDRICH,
Petitioner,

vs.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent.

PETITION FOR A WRIT OF CERTIORARI
To the United States Court of Appeals
For the Sixth Circuit

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QUESTIONS PRESENTED

I. Whether the Health Care Financing Administration (HCFA) promulgated a substantive rule relating to the reimbursement of health care costs for chelation therapy, thus requiring them to abide by the notice-and-comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. Section 553.

II. Whether the summary application of the HCFA rule by the Secretary of the Department of Health and Human Services (HHS) deprived Petitioner of due process.

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The Petitioner, Michael J. Friedrich, respectfully prays that a writ of certiorari issue to review the judgment of the Court of Appeals for the Sixth Circuit entered in this proceeding March 7, 1990. (Note: Rehearing denial date).

OPINIONS BELOW

The Judgment and Opinion of the United States Court of Appeals for the Sixth Circuit appears in the Appendix, as does the Court's denial of a Petition for Rehearing and the Memorandum Opinion of the United States District Court for the Northern District of Ohio and the Findings of Fact, Conclusions and Order of the Medicare Hearing Officer.

JURISDICTION

The judgment of the United States Court of Appeals for the Sixth Circuit was entered on January 25, 1990. The Petitioner's request for a rehearing was denied on March 7, 1990. This petition has been filed within ninety (90) days of the March 7, 1990 judgment. This Court's jurisdiction is invoked under 28 U.S.C. Section 1254.

CONSTITUTIONAL PROVISION INVOLVED

The constitutional challenge in this case is under the Due Process Clause, Fourteenth Amendment, of the United States Constitution: No state shall "deprive any person of life, liberty, or property, without due process of law . . ."

STATEMENT OF THE CASE

In 1976, Petitioner, Michael J. Friedrich, underwent double by-pass surgery, and in 1980, suffered an attack of angina. He was seen by a physician at the Cleveland Clinic and was informed that there was nothing further that could be done to improve his condition. In 1983, he came under the care of Dr. Frackelton, who began administering chelation therapy. The Petitioner suffered no further attacks of angina, and because his condition improved, continued to receive chelation therapy.

When the claims were submitted to the carrier, they were denied as non-covered services. The Petitioner requested a review of claims, and the original determination was upheld. A further hearing was requested, and on March 19, 1984, that hearing was held. Objection was made by the Petitioner to the fact that even though he was required to submit substantial evidence showing that the treatment which he received was both reasonable and necessary for the treatment of his disease, the hearing officer would deny the claim and not consider such evidence based upon the Secretary's instruction.

The claims were denied, with the hearing officer stating as follows:

* * *

> Although the evidence and testimony presented at this hearing was impressive and implies that the efficacy of chelation therapy as a viable alternative to conventional treatment for coronary artery disease, this does not alter the instructions contained in the carrier's manual that EDTA chelation therapy for the treatment or prevention of

> atherosclerosis is not covered. The coverage determinations are part of the instructions and guidelines issued to the carriers by the Secretary (sic) of the Department of Health and Human Services or his delegate.
>
> * * *

Petitioner then filed an action in the United States District Court for the Northern District of Ohio, contending that the mandatory application of the instruction violated due process. Petitioner also contended that the instruction was invalid because it was not issued pursuant to the rulemaking requirements of the Administrative Procedure Act (APA), 5 U.S.C. Section 553 (1982) and challenged the instruction on substantive grounds.

The parties cross-moved for summary judgment and the district court granted Petitioner's motion on the ground that the chelation therapy instruction was not issued pursuant to APA rulemaking requirements and was therefore invalid, at least as applied to Petitioner's claims for payment. The court ruled that the Social Security Act, 42 U.S.C. Section 1395ff (b)(3)(B), which bars a court from overturning a "national coverage determination" on the ground that APA rulemaking requirements were not followed, does not apply to Petitioner's claims since those claims related to services furnished prior to the January 1, 1987, effective date of the statute.

The district court further found that the 1982 instruction was a "substantive" rather than an "interpretative" rule, and therefore "subject to APA rulemaking requirements, on the ground opposed to a mere clarification of an existing regulation." The district court based this conclusion on its finding that "[p]rior to

1982, the Secretary permitted Medicare coverage of chelation therapy." In making this finding, the district court relied on a 1975 decision of the Appeals Council in a Part A case that allowed a beneficiary's claim for inpatient hospital services furnished in connection with chelation therapy treatments. The district court also cited the fact that from 1980 to 1982 Part A intermediaries and Part B carriers had authority to make their own determinations regarding coverage of chelation therapy.

Finally, the district court held that the mandatory application of the 1982 instruction of Petitioner's claims violated due process. The district court determined that Petitioner was deprived of a meaningful opportunity to present his case and of his right to a detached and neutral decision maker, since the carrier hearing officer was bound by the invalid chelation therapy instruction. The district remanded the case for a new hearing in which the 1982 instruction would have no force and effect.

The Respondent appealed the district court's decision. The Court of Appeals for the Sixth Circuit reversed the district court, finding the regulation to be interpretative and consistent with prior rulings on the use of chelation therapy. The court of appeals further held that no unconstitutional interference resulted from the application of this regulation.

REASON FOR GRANTING THE WRIT

This case gives the court an opportunity to create a standard of review to be applied when due process violations result from an administrative agency's failure to adhere to the procedural requirements imposed by Congress for the issuance of substantive rules.

I. THE HEALTH CARE FINANCING ADMINISTRATION PROMULGATED A SUBSTANTIVE RULE RELATING TO THE REIMBURSEMENT OF HEALTH CARE COSTS FOR CHELATION THERAPY, THUS REQUIRING THEM TO ABIDE BY THE NOTICE-AND-COMMENT REQUIREMENTS OF THE ADMINISTRATIVE PROCEDURE ACT.

The Administrative Procedure Act (APA) requires government administrative agencies to publish notice of all proposed substantive rules in the Federal Register, allowing an opportunity for interested persons to exercise their "right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. Section 553. The notice requirement and opportunity to respond which is established by the APA applies to substantive rules, but not to interpretive rules. 5 U.S.C. Section 553(b)(3)(A). What may constitute a substantive or an interpretive rule, however, is a matter of some controversy. The United States Court of Appeals for the Sixth Circuit admitted in its opinion concerning the instant case that "[w]e have discovered no bright line that separates the two types of rules." *Friedrich v. Secretary of Health and Human Services*, 894 F.2d 829, 834 (6th Cir. 1990). The court went on, however, to quote

the United States Court of Appeals for the District of Columbia which provided more insight into the distinction between the two rules by stating:

> First, the agency's own label, while relevant, is not dispositive ... An interpretive rule simply states what the agency thinks the statute means, and only "reminds" affected parties of existing duties ... On the other hand, if by its action the agency intends to create new law, rights or duties, the rule is properly considered to be a legislative rule.

Id., at 834. Citing *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984), *cert. denied*, 471 U.S. 1074 (1985) (citation omitted). The Sixth Circuit has repeatedly used this rule in their jurisdiction, although its application has met with differing results. *See, State of Ohio Department of Human Services v. United States Department of Human Services*, 862 F.2d 1228 (6th Cir. 1988). The further application of this rule to the instant case demonstrates that the rule considering chelation therapy which was set forth by the Secretary was "legislative" as defined in *General Motors*.

Under Part B of the Medicare Act, 42 U.S.C. Section 1395 *et seq.* (1982), reimbursement is denied for medical services which are not "reasonable and necessary for the diagnosis or treatment" of a claimant's illness or injury. 42 U.S.C. Section 1395 y(a)(1). Prior to 1980, the determination as to what was reasonable and necessary was made on a case by case basis by the insurance carrier. In 1980, however, the Secretary began the practice of examining some drugs individually and issuing national coverage determinations for the selected drugs which are binding upon insurance carriers and their hearing officers. Such a procedure was employed in the present case.

Although the Sixth Circuit recognized the binding effect of the national coverage determination, it nonetheless found the instruction to be interpretive rather than substantive. Such a result is incompatible with the *General Motors* rule because if the instruction "simply states what the agency thinks the statute means" it should not be given the full force of law; but instead, should be open to challenge. Since the national coverage determination is binding upon all insurance carriers and their hearing officers, it in fact "creates new law" consistent with the *General Motors* definition of a "legislative" or "substantive" rule. For this reason, the rule relating to chelation therapy should be viewed as a substantive rule which is subject to the notice-and-comment requirements of the APA.

II. THE SUMMARY APPLICATION OF THE HFCA RULE BY THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES DEPRIVED PETITIONER OF DUE PROCESS.

While Petitioner would not concede that the rule under consideration herein is merely interpretive, for the sake of argument on the due process issue, he will do so. The rule in *General Motors,* which the Sixth Circuit based their holding on, states that "[a]n interpretive rule simply states what the administrative agency *thinks* the statute means . . ." 742 F.2d at 1656 (emphasis added). If the justification for the holding in the instant case is that the HCFA "thinks" that chelation therapy for atherosclerosis is not "reasonable and necessary" pursuant to Part B of the Medicare Act, the Sixth

Circuit's holding has a very shallow basis. Such a justification should not be the basis for denial of a claim without an opportunity for a hearing. Petitioner could not have received a meaningful opportunity to be heard if the decision maker was bound by an instruction prohibiting reimbursement which, properly, was only "advisory" in nature.

Petitioner suggests that the purpose behind APA compliance is to ensure that the rules which result are fair, and therefore properly binding on all parties. Interpretive rules are exempted from compliance with the APA, therefore they should not be binding and should not carry the full force and effect of law. Such rules should remain, as their title suggests, an advisory interpretation of the actual law which may be applied on a case by case basis by the carriers, taking into consideration the diverse and complex situations which may be present in an individual claim.

The Due Process clause of the Fourteenth Amendment provides that no state shall "deprive any person of life, liberty, or property, without due process of law . . ." U.S. Const. Amend. XIV, Section 1. If interpretive rules are to be imposed in such a summary fashion and applied as if they were law, they must also be subject to the APA notice-and-comment requirement. If they are not subject to the APA requirements they cannot be binding in all cases. Due Process requires no less.

CONCLUSION

This case presents the Court with the opportunity to clearly and unequivocally create a standard of review to be applied when an administrative agency violates due process because of its failure to adhere to the procedural requirements imposed by Congress for the issuance of substantive rules. Such a standard of review is ripe for consideration by the Court. A ruling is desperately needed which will clear up the "considerable smog" which enshrouds the issue of what constitutes a "substantive" or "interpretive" agency rule. In addition, Constitutional guarantees of due process must be applied to hearings which consider interpretive rules so that they are not given the full force of law and summarily executed.

Respectfully submitted,

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APPENDIX

OPINION OF THE COURT OF APPEALS FOR THE SIXTH CIRCUIT

(Decided January 25, 1990)

RECOMMENDED FOR FULL TEXT PUBLICATION
See Sixth Circuit Rule 24

No. 89-3236

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

MICHAEL J. FRIEDRICH,
Plaintiff-Appellee,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Defendant-Appellant.

ON APPEAL from the United States District Court for the Northern District of Ohio

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Decided and Filed January 25, 1990

Before: MILBURN and GUY, Circuit Judges; and LIVELY, Senior Circuit Judge.

LIVELY, Senior Circuit Judge. This case concerns a claimant's right to reimbursement under Part B of the Medicare Act, 42 U.S.C. § 1395 *et seq.* (1982), for a medical procedure that the Secretary of Health and Human Services (the Secretary) has found not to be "reasonable and necessary for the diagnosis or treatment" of the claimant's particular illness. 42 U.S.C. § 1395y (a)(1). The appeal presents two questions for decision: (1) Whether a "national coverage determination" by the Secretary is invalid if promulgated without compliance with the notice and comment requirements of the Administrative Procedure Act (APA), 5 U.S.C.

§ 551 *et seq.* (1982); and (2) whether a hearing before an officer who is bound by such a determination violates due process.

I.

A.

The Medicare Act consists of two parts or programs. Part A provides insurance against the cost of institutional health services. Part B, the portion at issue here, is a voluntary, supplemental medical insurance program that covers 80 percent of the "reasonable charge" for a number of services, including certain physician services, x-rays, lab tests and medical supplies. The purpose of this section is to complement existing insurance coverage for the aged and disabled. Part B is financed through monthly fee charges to the beneficiaries and funding from the government. Thus, Part B may be said to resemble "a private medical insurance program that is subsidized in major part by the Federal Government." *Schweiker v. McClure,* 456 U.S. 188, 190 (1982).

Because of the substantial dimensions of the program, Part B is managed for the Secretary by "carriers," insurance companies who administer the payment of qualifying claims. The Secretary pays the carriers' costs resulting from claims administration and the carriers, acting as the Secretary's agents, in turn determine whether a claimed item or service is covered by the program. The carriers make this determination in strict accordance with the Medicare statute and the regulations, instructions and guidelines promulgated by the Secretary. 42 C.F.R. part 405, subpart H (1980).

Of particular relevance to this case is the fact that under Part B, the Secretary and the insurance carriers are required to deny reimbursement for services that are not "reasonable and necessary for the diagnosis or treatment" of a claimant's illness or injury. 42 U.S.C. § 1395y(a)(1). A finding of what services are "reasonable and necessary" is often made on a

case-by-case basis by the carrier. In more difficult cases, however, the Health Care Financing Administration (HCFA), a component of the Department of Health & Human Services (HHS), will make an assessment and then issue a "national coverage determination" clearly indicating to the carriers whether the particular item should be considered covered or not. National coverage determinations issued by HCFA are published in the Part B Carriers Manual (the Manual) and are therefore binding on the carriers and their hearing officers. 42 U.S.C. § 405.860.

In making its assessment of reasonableness and necessity HCFA often relies on the Public Health Service (PHS) for an evaluation of the safety and effectiveness of a particular service and the extent to which it has been accepted by the medical community. Within PHS, every review of this kind is undertaken by the Office of Health Technology Assessment (OHTA) of the National Center for Health Services Research and Health Care Technology Assessment (NCHSRHCTA). OHTA usually places a notice in the Federal Register announcing that an assessment is underway and soliciting comments from interested parties. During the assessment process OHTA also seeks information and recommendations from governmental agencies such as the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). OHTA also consults with professional organizations and medical specialty groups to determine whether the procedure is generally accepted by the medical community as being safe and effective, and conducts a review of the medical literature. HCFA then issues a national coverage determination based on its consideration of PHS's recommendations.

B.

The service at issue here, chelation therapy, is a treatment for atherosclerosis (obstructed arteries). The treatment consists of intravenous injections of disodium edetate solution. Proponents of the treatment believe that the disodium ede-

tate, which binds ("chelates") with calcium, removes the calcium-containing plaque that clogs arteries. According to the government, however, this treatment has been widely discredited by the general medical community as being ineffective and unsafe.

An examination of the record indicates that as early as 1970, HCFA had issued instructions restricting Medicare coverage of disodium edetate to treatment for hypercalcemia, ventricular arrhythmias, heart block associated with digitalis toxicity and scleroderma. This position was apparently embraced at the urging of PHS, which had consulted with various medical organizations and the FDA. As early as 1970 the FDA-approved labeling for the drug stated that disodium edetate was indicated for the severe conditions mentioned above, but not "for the treatment of generalized arteriosclerosis associated with advancing age." 35 Fed. Reg. 437, 438 (January 13, 1970).

The HCFA instructions on disodium edetate remained in effect until 1980, when HCFA replaced most specific drug coverage determinations with general criteria for intermediary and carrier use in determining coverage. The new 1980 criteria permitted payment for any use of an FDA-approved drug determined by the carrier to be reasonable and necessary, except for those uses specifically disapproved by the FDA or for which coverage might be precluded by a national instruction.

Subsequent to the issuance of the 1980 Carriers Manual, HCFA requested that NCHSRHCTA review chelation therapy and make a recommendation as to Medicare coverage. NCHSRHCTA published a notice in the Federal Register announcing its planned assessment and requesting interested parties to submit relevant information. 45 Fed. Reg. 41, 222 (June 18, 1980). NCHSRHCTA additionally sought evaluations of chelation therapy from a number of professional organizations and medical specialty groups. As a result of this

notice a large number of opinions by physicians and various medical organizations were obtained. Based on this information, NCHSRHCTA issued a comprehensive report and assessment recommending that the Medicare program not cover chelation therapy.

HCFA responded to the assessment by issuing a national coverage determination in February 1982 instructing intermediaries and carriers not to pay for chelation therapy under Medicare. These instructions appeared at two places in the Carriers Manual, in the treatment portion and in the drug portion:

> 35-64 Chelation Therapy for Treatment of Atherosclerosis — Not Covered (Effective date: *March 15, 1982*)
>
> Chelation therapy is the application of chelation techniques for the therapeutic or preventive effects of removing unwanted metal ions from the body. The application of chelation therapy using ethylenediamine-tetra-acetic acid (EDTA) for the treatment and prevention of atherosclerosis is controversial. There is no widely accepted rationale to explain the beneficial effects attributed to this therapy. Its safety is questioned and its clinical effectiveness has never been established by well designed, controlled clinical trials. It is not widely accepted and practiced by American physicians. EDTA chelation therapy for atherosclerosis is considered experimental. For these reasons, EDTA chelation therapy for the treatment or prevention of atherosclerosis is *not covered.*
>
> Some practitioners refer to this therapy as chemoendarterectomy and may also show a diagnosis other than atherosclerosis, such as arteriosclerosis or calcinosis. Claims employing such variant terms should also be denied under this section.

45-20 Ethylenediamine-Tetra-Acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis — Not Covered (Effective date: *March 15, 1982*)

The use of EDTA as a chelating agent to treat atherosclerosis, arteriosclerosis, clacinosis, or similar generalized condition not listed by the FDA as an approved use is not covered. Any such use of EDTA is considered experimental.

II.

The plaintiff Michael J. Friedrich, a Medicare Part B beneficiary, requested reimbursement for expenses related to chelation therapy. Friedrich received these treatments in February, March and April of 1983. The total cost of these services was $410.70. The plaintiff's insurance carrier, Nationwide Mutual Insurance (Nationwide) refused to reimburse the claimant for these expenses.

On May 19, 1983, plaintiff filed a claim with Nationwide seeking review of the earlier denial of his claim. The plaintiff's claim was again denied by letter on June 24, 1983. On July 25, 1983, Friedrich requested a carrier hearing review. This hearing was held on March 19, 1984. At the hearing both the plaintiff and his physician, Dr. Frackleton, testified as to the benefits of chelation therapy for the treatment of atherosclerosis. The witnesses also submitted written material. The Secretary offered no contrary evidence. On April 25, 1984, the hearing officer found that "[a]lthough the evidence and testimony presented at this hearing was impressive and implies the efficacy of chelation therapy as a viable alternative to conventional treatment for coronary artery disease, this does not alter the instructions contained in the carrier's manual that EDTA chelation therapy for the treatment or prevention of atherosclerosis is not covered." Reimbursement was denied on this basis.

Friedrich appealed this decision to the district court by filing a complaint and an amended complaint in November

1984. The Secretary responded and later filed a motion for judgment on the pleadings questioning federal jurisdiction. By agreement of the parties, the case was assigned to a magistrate for trial and decision. On May 1, 1987, the magistrate determined that he had jurisdiction to hear the case. He then proceeded to consider cross-motions for summary judgment subsequently filed by the parties. In his Memorandum and Order dated January 10, 1989, the magistrate found for the plaintiff.

The plaintiff had argued that the Secretary's instructions violate the Administrative Procedure Act's "notice and comment" requirements. 5 U.S.C. § 533. The defendant, on the other hand, argued that the magistrate was prevented from ruling that the Secretary's order was invalid because a provision of the Omnibus Budget Reduction Act of 1986 (OBRA), which amended the Medicare Act, precludes overturning national coverage determinations on the basis of a failure to conform to the notice and comment requirements of the APA. The magistrate, however, found that the OBRA is not applicable in this case because by its own language it only applies to "items or services furnished on or after January 1, 1987." Pub. L. No. 99-509, § 9341(b), 100 Stat. 1874, 2037-38 (1986); see also 42 U.S.C. § 1395ff (1982 ed. and Supp. V) (note regarding effective date of 1986 amendment). Since the plaintiff's chelation therapy was administered well before January 1, 1987, the magistrate concluded that he was not barred from overturning the Secretary's decision in this case.

The magistrate also noted that the OBRA contains a provision exempting from challenge rules or instructions associated with payment determinations issued before January 1, 1981. 42 U.S.C. § 1395ff(b)(4). This provision was found to be ineffective as to the challenged instructions because they were issued after January 1, 1981. In fact, they were issued on March 15, 1982.

The magistrate further held, for essentially the same reasons, that the OBRA did not preclude federal jurisdiction of the issue, citing *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), which held that judicial review of a carrier's Part B benefit determination is available when a beneficiary challenges the validity of the regulation or instructions upon which the carrier's determination is based.

The magistrate then went on to hold that APA provisions requiring publication of proposed agency rules of a substantive nature in the Federal Register, followed by a public comment period prior to promulgating the proposed rule had been violated by the Secretary's determination. The magistrate concluded that the Secretary's rule was substantive, not interpretative, because it effected a change in existing law and policy.

The magistrate also found that the mandatory application of the 1982 instructions to the plaintiff's claims violated due process. He based this holding on the finding that the plaintiff had been deprived of a meaningful opportunity to present his case and of his right to a detached and neutral decision maker because the carrier hearing officer was bound by the "invalid" chelation therapy instruction.

The district court remanded the case for another hearing to determine whether Friedrich's claim should be honored under Part B of Medicare without considering the Secretary's instruction. HHS now appeals claiming that the district court erred in holding invalid the Secretary's national coverage determination barring Medicare payments for chelation therapy and in finding that the plaintiff was denied due process at his review hearing.

The parties have raised the same issues here as in the district court with somewhat expanded arguments and additional citations. We will discuss their positions as required for a decision.

III.

Disposing of the jurisdictional issue first, we agree with the magistrate that the district court did have jurisdiction over this case. In the absence of a showing of clear congressional intent to the contrary, there is a "strong presumption" in favor of judicial review of administrative action. *Bowen v. Michigan Academy*, 486 U.S. at 670. The Secretary contends that section 9341(a)(1) of OBRA placed explicit limitations on court review of national coverage determinations, thus overcoming the presumption. He relies on two subsections of section 9341(a)(1)(D), codified as 42 U.S.C. § 1395ff(b)(3) and (4) (1982 ed. and Supp. V):

> (3) Review of any national coverage determination under section 1395y(a)(1) of this title respecting whether or not a particular type or class of items or services is covered under this subchapter shall be subject to the following limitations:
>
> * * *
>
> (B) Such a determination shall not be held unlawful or set aside on the ground that a requirement of section 553 of title 5 or section 1395hh(b) of this title, relating to publication in the Federal Register or opportunity for public comment, was not satisfied.
>
> * * *
>
> (4) A regulation or instruction which relates to a method for determining the amount of payment under part B of this subchapter and which was initially issued before January 1, 1981, shall not be subject to judicial review.

Neither of these provisions applies to this case. Subsection (4) by its terms applies only to regulations or instructions issued before January 1, 1981. The national coverage deter-

mination of concern here was issued in 1982. It is true that subsection (3)(B) restricts judicial review by providing that a national coverage determination shall not be held unlawful on the ground that the Secretary has failed to comply with the notice and comment requirements of the APA. Section 9341(b) of OBRA states, however, that the amendments made by the subsection "shall apply [only] to items and services furnished on or after January 1, 1987." The plaintiff sought reimbursement only for services furnished prior to that date.

While conceding that the provisions limiting judicial review are not retroactive, the Secretary argues that we should apply them to pending cases, such as that of the plaintiff. We find no merit in this argument. Congress could have made the amendments applicable to pending cases, but chose an effective date in the future, and we are bound by that legislative decision. The district court had jurisdiction over this action.

IV.

Assuming the district court had jurisdiction, the Secretary contends that the national coverage determination that chelation therapy is not covered for Medicare reimbursement is valid, and that the district court erred in setting it aside for failure to comply with the requirements of the APA.

A.

The APA requires notice of proposed rule making and an opportunity for interested persons to participate. 5 U.S.C. §§ 553, 556. There is an exception to the notice and hearing requirements, however, for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice. . . ." 5 U.S.C. § 553(b)(A). The Secretary maintains that the national coverage determination relating to chelation therapy is an interpretative rule, the purpose of which is to define the application to one particular procedure

of the general statutory requirement that Medicare covers only those services considered "reasonable and necessary" in the diagnosis or treatment of an illness. 42 U.S.C. § 1395y(a)(1). The district court concluded that the determination is a "legislative" or "substantive" rule, and thus not within the exception relied upon by the Secretary.

We have discovered no bright line that separates the two types of rules. The United States Court of Appeals for the District of Columbia, because of its heavy administrative law caseload, has dealt with this issue in many decisions. Yet, that court has stated that the distinction between the two types of rules is " 'enshrouded in considerable smog.' " *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (quoting two earlier decisions), *cert. denied*, 471 U.S. 1074 (1985). The court attempted to penetrate this smog in *General Motors* by identifying "certain general principles" that may assist a court in determining whether a particular rule is legislative or interpretative. *Id.* The court stated these principles as follows:

> First, the agency's own label, while relevant, is not dispositive. . . . An interpretative rule simply states what the administrative agency thinks the statute means, and only " 'reminds' affected parties of existing duties." . . . On the other hand, if by its action the agency intends to create new law, rights or duties, the rule is properly considered to be a legislative rule.

Id. (Citations omitted). This court has stated its agreement with this approach in *State of Ohio Department of Human Services v. United States Department of Health & Human Services*, 862 F.2d 1228, 1234 (6th Cir. 1988), and *State of Michigan v. Thomas*, 805 F.2d 176, 182-83 (6th Cir. 1986). Applying these principles, the court found the rule in *State of Ohio* to be legislative and the rule in *Thomas* to be interpretative.

The *General Motors* court noted that the agency involved had characterized the rule as interpretative. 742 F.2d at 1565. The Secretary has treated the determination as interpretative in the present case. Such a characterization is important, though not conclusive in determining the true nature of a rule. *Levesque v. Block*, 723 F.2d 175, 182 (1st Cir. 1983); *American Postal Workers Union v. United States Postal Service*, 707 F.2d 548, 559 (D.C. Cir. 1983), *cert. denied*, 465 U.S. 1100 (1984). The court in *General Motors* found it "most important[ ]" that the rule it was considering created no "new rights or duties; instead, it simply restated the consistent practice of the agency. . . ." 742 F.2d at 1565.

B.

The plaintiff argues that the chelation therapy determination represented a departure from Medicare's general policy with respect to coverage. It argues that the general policy is to treat drugs approved for marketing by the FDA as satisfying the statutory "reasonable and necessary" requirement for Medicare reimbursement. He emphasizes the fact that a passage in the Manual states that the disqualification of chelation therapy is an exception to Medicare's general policy on coverage of drugs. The same statement continues, however, by stating that the general rule is to treat FDA-approved drugs prescribed by a physician as covered "if the Medicare contractor determines the use is reasonable and necessary. . . ." The Secretary asserts that the purpose of the determination was to restate the Department's consistent policy that, though considered reasonable and necessary for treatment of some illnesses, chelation therapy does not satisfy this statutory requirement when used for the treatment of atherosclerosis.

The record reveals that as early as 1970 the Department of Health, Education and Welfare had advised by notices in the Federal Register that disodium edetate was not considered effective for the treatment of generalized arteriosclerosis. (Atherosclerosis is a stage of the chronic disease arterio-

sclerosis). The Secretary states that this has been the consistent position of the Department and that the 1982 national coverage determination did not represent a change of position.

In 1980 the Secretary began the practice of examining some drugs individually rather than qualifying all FDA-approved drugs if they were found by the Part B carriers to be reasonable and necessary. The 1982 determination implemented this new policy. In effect, it made the determination of reasonableness and necessity with respect to a particular use of chelation therapy rather than leaving that determination to the carriers. The Secretary states that in doing so, he created no new rights or duties; he merely applied the statutory requirements to a particular use of a given drug and method of treatment. The "new policy" referred to in the Manual is the *method* of dealing wih FDA-approved drugs, not a new policy with respect to the reasonableness or necessity for use of chelation therapy in the treatment of atherosclerosis.

The plaintiff insists that the Secretary has not followed a consistent policy of denying Medicare coverage for chelation therapy. He cites a 1975 decision of the Appeals Council finding chelation therapy reasonable and necessary under Part A of the Medicare program for the treatment of atherosclerosis. We agree with the Secretary that this single decision by the Appeals Council is not significant. The Appeals Council made this decision in considering an individual claim for Part A reimbursement. In deciding the individual Part A claim the Appeals Council was not bound in any way by the instructions to carriers in deciding claims under Part B. The Appeals Council decision was not a " 'contemporaneous expression of opinion by [a] low-ranking official[ ],' " which courts have found " 'highly relevant and material evidence of the general understanding of ambiguous regulatory provisions.' " *State of Ohio,* 862 F.2d at 1235 (citations omitted). Rather it was a discrete decision made totally apart from the policy-making functions of the Secretary. The record as

a whole convinces us that the Secretary has been consistent in his determination that Chelation therapy is not reasonable and necessary for the diagnosis or treatment of atherosclerosis. Thus the 1982 determination did not represent a departure from a previous evaluation of this medical procedure.

The plaintiff also contends that the determination should be considered legislative or substantive because it has a substantial impact on a large number of Medicare beneficiaries. At an earlier time, substantial impact was treated by a number of courts as an important factor in deciding whether a rule was legislative or interpretative. More recent cases have held that the level of impact on interested parties is not a factor in correctly classifying a rule or regulation. *E.g., Postal Workers,* 707 F.2d at 560. This court recognized the substantial impact argument in *State of Ohio,* 862 F.2d at 1233-34, but chose not to make impact a basis for its characterization of the rule it was considering. We think this approach is sound in the present case. Any determination by the Secretary regarding rules for Medicare reimbursement eligibility, regardless of how it is promulgated, will have a substantial impact on a large number of people. The extent of the impact is not an indicative factor in our search for the proper characterization of the national coverage determination.

Finally, the plaintiff argues that the national coverage determination is a substantive or legislative rule because it "fills the gaps" in the Medicare Act. We cannot perceive how the determination may be considered a "gap-filling" rule. The statute does not list some medical procedures as qualifying and leave it to the Secretary to supplement the list. Rather, it prescribes a test for determining what procedures qualify — those that are reasonable and necessary. The Secretary's role is not to fill in gaps, but to apply the statutory standard to an enormous number of modern medical practices. Thus, the plaintiff's reliance on *Mason General Hospital v. Secretary of Health and Human Services,* 809 F.2d 1220 (6th Cir. 1987), is misplaced, since that case involved agency rulemaking

intended to fill in the spaces left by a complex legislative scheme.

C.

As previously noted, this court has applied the "general principles" enunciated by the D.C. Circuit in two recent cases with opposite results. In *State of Ohio,* the court found that a regulation establishing a "maintenance amount ceiling" for allocation of Medicaid funds was a legislative rule. Since the rule had not been promulgated in accordance with the APA's notice and comment requirements, the court found it invalid. The rule in question was issued in 1978 and the Department of Health & Human Services argued that it was interpretative because it only made explicit what had been implicit all along in a 1974 regulation. The state relied heavily on the fact that the Department had approved Ohio's "family budgeting system" in 1974, acting under the original regulation. The budgetary system approved in 1974 was inconsistent with the 1978 regulation, and indicated that the 1978 view concerning "maintenance amount ceiling" was not implicit in the 1974 regulation.

The court concluded that the 1978 regulation did not "remind" states of a pre-existing limitation on the application of funds, but mandated a new limitation. Rather than interpreting the meaning of an existing regulation, it imposed a new ceiling of its own force. 862 F.2d at 1234. The court found the 1974 approval significant as a contemporaneous interpretation of the then current regulation. This inconsistent treatment of two state submissions in *State of Ohio* was quite different from the alleged inconsistency relied upon by the plaintiff in the present case. In *State of Ohio,* the setting in which the Department made two inconsistent interpretations of a regulation was the same. In 1974, HHS approved the state's submission of a family budgeting system and in 1978 the agency refused to approve the submitted family budgeting system which was based on the same interpretation

of the 1974 regulation that had led to approval in 1974. The court found this inconsistency telling in its conclusion that HHS did much more in 1978 than interpret its 1974 regulation. On the other hand, the isolated Appeals Council decision adverted to by Friedrich was made in a totally different setting and indicated no inconsistency or break with an earlier position of the Secretary.

State of Michigan v. Thomas involved rules proposed by Michigan to control fugitive dust emissions. The Environmental Protection Agency (EPA) disapproved the proposal, and Michigan, along with a number of affected industries, petitioned this court for review of EPA's action. EPA's disapproval was in the form of a final rule which it issued without following the APA's notice and comment requirements. Citing *General Motors,* this court held that the rule in question was interpretative rather than legislative. It did not "create any new law, rights or duties." 805 F.2d at 183.

D.

This is a difficult case and not totally like any other we have been cited to or discovered. The Medicare program covers the full range of modern medicine and pharmacology. It is comprehensive and operates through a complex structure. National standards are essential if there is to be uniformity and equality in the administration of Medicare. The Secretary has chosen to seek uniformity by requiring Part B carriers to abide by all regulations in the Manual. It is inconceivable to us that the Secretary might be required to comply with the full panoply of APA notice and comment requirements in promulgating national standards for individual drugs and medical procedures. This is a classic case of a rule that fits perfectly the "common theme" of the § 553(b)(A) exception for rules that " 'accommodate situations where the policies promoted by public participation in rulemaking are outweighed by the countervailing considerations of effectiveness, efficiency, expedition and reduction in expense.' "

American Hospital Association v. Bowen, 834 F.2d 1037, 1045 (D.C. Cir. 1987), quoting *Guardian Federal Savings & Loan Association v. Federal Savings & Loan Insurance Corp.*, 589 F.2d 658, 662 (D.C. Cir. 1978).

The Medicare Act mandates that only reasonable and necessary medical services are reimbursable. The national coverage determination does not "fill the gaps" in the statute, *Postal Workers*, 707 F.2d at 559, or "supplement" it, *United Technologies Corp. v. United States Environmental Protection Agency*, 821 F.2d 714, 719 (D.C. Cir. 1987). Thus, it creates no new law. Rather, it interprets the statutory language "reasonable and necessary" as applied to a particular medical service or method of treatment. The district court erred in concluding that the determination is a legislative rule and therefore is invalid for failure of the Secretary to comply with the requirements of 5 U.S.C. § 553(b).

Having decided that the determination is within the APA's exception, we do not address the Secretary's argument that the procedures followed in implementing the regulation were the "functional equivalent" of notice and comment under the APA, or that Congress "endorsed" the Secretary's procedures for promulgating national coverage determinations by enacting in OBRA a prospective limitation on judicial review of such regulations.

V.

The magistrate held that the plaintiff was denied due process because the hearing officer was bound by invalid instructions based on the national coverage determination, stating:

> Friedrich was not given a meaningful opportunity. The hearing officer, though permitting Friedrich to offer evidence that his chelation therapy was medically reasonable, did not actually consider this evidence. The hearing officer was bound by the chelation therapy instructions of the carrier's manual.

> As noted earlier, these instructions were invalid. A meaningful opportunity in this case requires that the hearing officer rule on Friedrich's chelation therapy claim without considering the instructions.

We have found that the determination was valid. Thus, this ground for holding that the hearing abridged the plaintiff's right to due process is eliminated.

The magistrate also appears to have held that due process requires a hearing at which the officer is free to make a determination of coverage free of any binding instructions in the Manual, valid or invalid. We disagree.

The first step in deciding a procedural due process claim is to identify the interest to which the due process attaches. Here, Friedrich claimed a property interest in Medicare benefits and the magistrate agreed that he had such an interest. The Supreme Court has defined those property interests entitled to constitutional protection as "more than a unilateral expectation;" instead, a claimant must have "a legitimate claim of entitlement" to property. *Board of Regents v. Roth*, 408 U.S. 564, 577 (1972). The only legitimate claim of entitlement under Medicare is to those services that are reasonable and necessary. 42 U.S.C. § 1395(y)(a)(1). There is no legitimate claim of entitlement to a given medical procedure just because a doctor prescribes it or a patient requests it.

The record in this case reveals that the plaintiff had no more than a unilateral expectation that he would receive reimbursement under the Medicare program for chelation therapy. As we have noted, on advice of the PHS and others, the Secretary has ruled consistently since 1970 that this procedure is not safe and effective for the treatment of atherosclerosis. The various Federal Register notices and publications have consistently found that there is little support in the medical community for this course of treatment, and that at best it must be considered experimental. The change in the Secretary's method of evaluating medical procedures in

1980 did not produce a change in his position concerning chelation therapy. There was no basis for a legitimate claim of entitlement to this treatment since it had never been deemed "reasonable and necessary."

The record discloses that NCHSRHCTA received and considered large volumes of material, mostly anecdotal, in favor of chelation therapy before HCFA made its final evaluation and issued the national coverage determination in February 1982. We have found the evaluation procedure valid as meeting the requirements for promulgation of an interpretative rule. Friedrich does not have a due process right to have his individual claim considered *de novo* in the face of the Secretary's determination. Having made a national coverage determination, the Secretary is not required to defend it in response to individual claims by every person who disagrees with the decision to deny coverage. The fact that the hearing officer was bound by the determination did not deny Friedrich process to which he was due.

The judgment of the district court is reversed with directions to dismiss the complaint.

JUDGMENT ENTRY OF THE COURT OF APPEALS FOR THE SIXTH CIRCUIT

(Filed January 25, 1990)

No. 89-3236

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

MICHAEL J. FRIEDRICH,
Plaintiff-Appellee,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,
Defendant-Appellant.

Before: MILBURN and GUY, *Circuit Judges;* and LIVELY, *Senior Circuit Judge.*

JUDGMENT

ON APPEAL from the United States District Court for the Northern District of Ohio.

THIS CAUSE came on to be heard on the record from the said district court and was argued by counsel.

ON CONSIDERATION WHEREOF, It is now here ordered and adjudged by this court that the judgment of the said district court in this case be and the same is hereby reversed with directions to dismiss the complaint.

Each party is to bear its own costs on appeal.

ENTERED BY ORDER OF THE COURT

/s/ LEONARD GREEN
Clerk

Issued as Mandate: March 15, 1990

MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT

(Filed January 10, 1989)

C84-2022

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

MICHAEL J. FRIEDRICH,
Plaintiff,

v.

OTIS R. BOWEN, SECRETARY OF HEALTH AND HUMAN SERVICES,
Defendant.

MEMORANDUM AND ORDER

STREEPY, *Mag.*

Plaintiff Michael J. Friedrich, a Medicare Part B beneficiary, sought and was denied reimbursement for chelation therapy he paid for as treatment of his atherosclerosis in 1983. Friedrich challenges the denial, principally contending that the defendant, the Secretary of Health and Human Services (Secretary) violated the Administrative Procedure Act (A.P.A.). Additionally, Friedrich claims a due process violation.

It is first necessary to briefly review the history of the Medicare program, especially the Part B program. Medicare was established in 1965 under Title XVIII of the Social Security Act and consists of two parts. *See* 42 U.S.C. §1395, *et seq.* Part A is a mandatory hospital insurance program financed through employment taxes.

Part B is a voluntary supplemental medical insurance program financed through monthly fees charged to those opting for the service.

Part A provides limited medical coverage for persons who are disabled or are under the Social Security Retirement Program. 42 U.S.C. §1395. It covers the cost of inpatient hospital care and some post-hospital care. 42 U.S.C. §§1395c-1395i-3. Part A is administered by the Secretary through "intermediaries," who are insurance companies under contract with the Secretary who both review beneficiary claims and determine the amounts to be paid for the medical services. An individual dissatisfied with the decision of an intermediary is entitled to an administrative hearing before the Secretary and to judicial review. 42 U.S.C. §1395ff(b)(1).

Part B coverage is a voluntary, supplemental medical insurance program available to those persons who qualify for Part A coverage and opt for the additional coverage by paying a monthly fee. Part B covers 80 percent of the "reasonable charge" for a number of services, including physician services, x-rays, lab tests, medical supplies and certain medical equipment. 42 U.S.C. §§1395k, 1395l, 1395x. Part B is financed through monthly fees charged to the beneficiaries and subsidies from the federal government. Part B is managed for the Secretary through "carriers." Carriers are insurance companies who administer the payment of qualifying claims. 42 U.S.C. §1395u.

Upon receiving a claim, the Part B carrier must determine whether the claimed item or service is covered by the program. In making this determination, the carrier must decide whether the service or item is medically necessary, otherwise covered by the Part B program, and establish the reasonable charge. 42 U.S.C. §1395u; 42 C.F.R. §§405.803, 421.200.

If a claim is denied by a carrier, and is for $100 or more, the claimant may seek an evidentiary hearing before a hearing officer chosen by the carrier. 42 U.S.C. §1395u. The hearing officer receives evidence, hears oral arguments, and then issues a written decision setting forth his findings of fact and statement of reasons. 42 C.F.R. §405.834. In reaching his decision, the hearing officer "is to comply with all the provisions of Title XVIII of the [Social Security] Act and regulations issued thereunder, as well as with all policy statements, instructions and other guide[lines]" issued by the Secretary. 42 C.F.R. §405.860. The Secretary has issued a Medicare Carrier's Manual (hereinafter carrier's manual), which sets forth instructions as to specific types of claims.

Friedrich received a series of seven chelation therapy treatments and a urinalysis test[1] during the period from February 1, 1983 through April 23, 1983.[2] Shortly after each treatment, he filed a claim with Nationwide Mutual Insurance (Nationwide), the Part B Medicare carrier in Ohio. He was denied reimbursement for each claim. See Def. Ex. 1.

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[1] The urinalysis is a metal analysis of the plaintiff's urine and related to the chelation treatments. See defendant's exhibit 1, plaintiff's claims and carrier determination (Def. Ex. 1). This charge was also denied.

[2] The claims at issue are:

Type of Treatment	*Date of Claim*	*Date of Treatment*	*Charge*
Chelation	2/2/83	2/1/83	$ 55.00
Urinalysis	2/3/83	2/3/83	25.70
Chelation	2/19/83	2/18/83	55.00
Chelation	3/7/83	3/4/83	55.00
Chelation	3/18/83	3/18/83	55.00
Chelation	4/2/83	4/1/83	55.00
Chelation	4/19/83	4/14/83	55.00
Chelation	5/12/83	4/29/83	55.00
		TOTAL	$410.70

On May 19, 1983, Friedrich filed a claim with Nationwide seeking review of the earlier denial of claims for outpatient chelation therapy and a related urine test. On June 24, 1983 Nationwide denied his May 19, 1983 claim by letter. See defendant's exhibit 3, carrier decision on review, June 24, 1983 (Def. Ex. 3). The letter also advised Friedrich of his right to a hearing on the matter before one of the carrier hearing officers. *Id.*

On July 25, 1983 Friedrich requested a carrier hearing review. *See* defendant's exhibit 4, plaintiff's request for carrier hearing, July 25, 1983 (Def. Ex. 4). The carrier hearing was held on March 19, 1984. *See* defendant's exhibit 5, p. 45, decision of carrier hearing officer, April 25, 1984 (Def. Ex. 5). At the hearing both Friedrich and Dr. Frackleton, the doctor who administered the chelation therapy, testified as to the benefits of chelation for the treatment of atherosclerosis. Friedrich also submitted several articles and pamphlets about the benefits of chelation. *Id.* at 7, 14. There was no evidence set forth to rebut the plaintiff's evidence, but there were relevant carrier manual instructions.

On April 25, 1984, the hearing officer found that "[a]lthough the evidence and testimony presented at this hearing was impressive and implies the efficacy of chelation therapy as a viable alternative to conventional treatment for coronary artery disease, this does not alter the instructions contained in the carrier's manual that EDTA chelation therapy for the treatment or prevention of atherosclerosis is not covered." Def. Ex. 5, p. 59. The hearing officer denied coverage based on the manual.

The carrier's manual, referred to and relied on by the hearing officer, is a volume of instructions promulgated by the Secretary. These instructions are considered to be

binding on the carrier in arriving at a decision on whether a claim is or is not covered by Medicare. 42 C.F.R. §405.860.

The instructions in the carrier's manual that the hearing officer relied on state:

> 45-20 Ethylenediamine-Tetra-Acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis—Not Covered (Effective date: *March 15, 1982*)
>
> The use of EDTA as a chelating agent to treat atherosclerosis, arteriosclerosis, calcinosis, or similar generalized condition not listed by the FDA as an approved use is not covered. Any such use of EDTA is considered experimental.
>
> See section 35-64 for an explanation of this conclusion.
>
> 35-64 Chelation Therapy for Treatment of Atherosclerosis—Not Covered (Effective date: *March 15, 1982*)
>
> Chelation therapy is the application of chelation techniques for the therapeutic or preventive effects of removing unwanted metal ions from the body. The application of chelation therapy using ethylenediamine-tetra-acetic acid (EDTA) for the treatment and prevention of artherosclerosis is controversial. There is no widely accepted rationale to explain the beneficial effects attributed to this therapy. Its safety is questioned and its clinical effectiveness has never been established by well designed, controlled clinical trials. It is not widely accepted and practiced by American physicians. EDTA chelation therapy for atherosclerosis is considered experimental. For these reasons, EDTA chelation therapy for the treatment or prevention of atherosclerosis is *not covered*.

> Some practitioners refer to this therapy as chemo-endarterectomy and may also show a diagnosis other than atherosclerosis, such as arteriosclerosis or calcinosis. Claims employing such variant terms should also be denied under this section.

Friedrich appealed the carrier's decision to this court by filing a complaint followed on November 19, 1984, by an amended complaint. Shortly thereafter, the Secretary filed a motion for judgment on the pleadings questioning federal jurisdiction. On May 1, 1987 this court ruled it had jurisdiction to hear this case under the Supreme Court decision in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). Presently pending are cross motions for summary judgment.

Although summary judgment is a useful and often efficient device for deciding cases, it must be used only with extreme caution for it operates to deny a litigant his day in Court. *Poller v. Columbia Broadcasting System, Inc.*, 368 U.S. 464, 467 (1962); *Tee-Pak, Inc. v. St. Regis Paper Co.*, 491 F.2d 1193, 1196 (6th Cir. 1974). Thus on a motion for summary judgment the moving party has the burden of showing conclusively that there exists no genuine issue as to a material fact and the evidence together with all inferences to be drawn therefrom must be read in the light most favorable to the party opposing the motion. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157, 158-159 (1970); *United States v. Diebold*, 369 U.S. 654, 655 (1962); *United States v. Articles of Device, etc.*, 527 F.2d 1008, 1011 (6th Cir. 1976). Indeed, while the papers of the moving party are to be closely scrutinized, those of the opponent are to be viewed indulgently. *Bohn Aluminum & Brass Corp. v. Storm King Corp.*, 303 F.2d 425, 427 (6th Cir. 1962).

Friedrich challenges the previously quoted instructions which deny Part B coverage of chelation therapy for the treatment of atherosclerosis, claiming violations of both the A.P.A. and the Due Process Clause.

A.P.A.

Friedrich argues that the carrier manual instructions 35-64 and 45-20 are substantive rules and should have been promulgated pursuant to the notice and comment requirements of the A.P.A. The instructions did not follow that procedure, but the Secretary contends recent amendments to the Social Security Act contained in the Omnibus Budget Reduction Act of 1986 (O.B.R.A.) preclude judicial review of carrier manual instructions. The Secretary also contends that the A.P.A. does not apply in this case because the instructions are interpretative.

Impact of the O.B.R.A.

The Secretary contends that national coverage determinations such as the chelation therapy instructions at issue may not be challenged for failure of the Secretary to conform to all the A.P.A. requirements. The Secretary relies on the O.B.R.A., which precludes overturning national coverage determinations on the basis of the failure to conform to the notice and comment procedures of the A.P.A. 42 U.S.C. §1395ff(b)(3).

The O.B.R.A. postdates the chelation treatments at issue in this case. It explicitly applies only to "items or services furnished *on or after* January 1, 1987." (Emphasis added.) See Omnibus Budget Reconciliation Act of 1986, Pub.L.No. 99-509, §9341(b), 100 Stat. 1874, 2037-38 (1986). The chelation services in this case were

administered over a period from February 1983 through April 1983, more than four years prior to January 1, 1987.

There is a presumption that legislation applies only prospectively in the absence of language to the contrary. *United States v. Estate of Donelly,* 397 U.S. 286 (1970); *Cox v. Schweiker,* 684 F.2d 310 (5th Cir. 1982). There is no language in the O.B.R.A. stating that the statute has general retroactive application, but one provision does exempt from challenge and review methodology determinations issued before January 1, 1981. See 42 U.S.C. §1395ff(b)(4). This provision does not affect the chelation instructions at issue since they were issued after January 1, 1981, on March 15, 1982.

The Secretary argues that the O.B.R.A. also bars federal jurisdiction of the plaintiff's claim. *Michigan Academy, supra,* held judicial review of a carrier's Part B benefit determination is available when a beneficiary challenges the validity of the regulation or instructions upon which the carrier's determination is based. The Secretary contends that the enactment of O.B.R.A. in 1986 changed the assumption of congressional intent underlying the *Michigan Academy* decision, thus precluding plaintiff's present challenge.

Under O.B.R.A., Congress clearly intended to preclude judicial review of the Secretary's national coverage determinations issued on or after January 1, 1987 for their failure to comply with the A.P.A. 42 U.S.C. §1395ff(b)(3). However, Friedrich is challenging Part B determinations made in 1983, three years prior to enactment of O.B.R.A. There is no provision in the O.B.R.A. which states section 1395 ff(b)(3) has a retroactive effect. In fact, the legislative history of O.B.R.A. does not even mention the *Michigan Academy*

decision. H.R. Rep. No. 727, 99th Cong., 2nd Sess. 95-6, *reprinted in* 1986 U.S. Code Cong. & Admin. News 3607, 3685-86; S.Rep. No. 348, 99th Cong., 2nd Sess. 350-51, *reprinted in* 1986 U.S. Code Cong. & Admin. News, 3607, 3995-96; H.R. Conf. Rep. No. 1012, 99th Cong., 2nd Sess., *reprinted in* 1986 U.S. Code Cong. & Admin. News 3607.

Notice and Comment Requirements

The A.P.A. requires publication of proposed agency rules in the Federal Register, followed by a public comment period prior to promulgating the proposed rule as a final regulation. 5 U.S.C. §533. These requirements apply to substantive rules only. 5 U.S.C. §552(a)(1)(D). Interpretative rules are exempt from the notice and comment provision of the A.P.A. 5 U.S.C. §553(b)(3)(A). Therefore, in determining whether the notice and comment provisions of the A.P.A. apply in this case, it is necessary to distinguish interpretative rules from substantive rules.

"Interpretative rules are those which merely clarify or explain existing law and regulations." *Powderly v. Schweiker,* 704 F.2d 1092, 1098 (9th Cir. 1983). Interpretative rules do not grant rights, impose obligations or produce other significant impacts on private interests. *General Motors Corp. v. Ruckelshaus,* 742 F.2d 1561 (D.C.Cir. 1984), *cert. denied, General Motors Corp. v. Thomas,* 471 U.S. 1079 (1985). Interpretative rules only explain what the more general words of the Act or regulation provide. *Powderly,* 704 at 1098. Substantive rules are those which effect a change in existing law or policy. *Gosman v. United States,* 573 F.2d 31, 39 (Ct.Cl. 1978). Substantive rules do more than explain law, they "create law." *Cabais v. Egger,*690 F.2d

234, 238 (D.C.Cir. 1983); *Bio-Medical Applications of Providence, Inc. v. Heckler,* 593 F.Supp. 1233 (D.C.C. 1984), *aff'd without opn.* 776 F.2d 365; *see generally, State of Ohio v. Department of HHS,* _____ F.2d _____, No. 86-3449 (6th Cir. November 28, 1988).

Section 45-20 of the carrier's manual provides that chelation therapy for the treatment of atherosclerosis is not reasonable and necessary, thus not a covered service, because it is "... controversial ... [i]ts safety is questioned ... its clinical effectiveness has never been established ... [and it] is considered experimental." The hearing officer found he was bound by this instruction, thus he denied plaintiff's claim to be reimbursed for the chelation therapy.

The regulation upon which the instruction at issue is based provides for the exclusion from coverage of those services "not reasonable and necessary ... for the diagnosis and treatment of illness or injury." 42 C.F.R. §405.310(u). This regulation in turn is based on the statute which provides in similar language that "no payment may be made under Part A or Part B ... for items or services ... not reasonable and necessary for the diagnosis or treatment of illness or injury...." 42 U.S.C. §1395y(a)(1)(A).

The instructions at issue were promulgated in 1982. Prior to 1982, the Secretary permitted Medicare coverage of chelation therapy for the treatment of atherosclerosis. As early as 1975, the Appeals Council of the Social Security Administration found chelation therapy was reasonable and necessary under Part A for the treatment of atherosclerosis. The Appeals Council found that "when chelation therapy was decided as the proper course of treatment, it was reasonable and necessary that these treatments be given the claimant on an

inpatient basis so his condition could be properly monitored." The Appeals Council concluded that Medicare could pay for chelation therapy for the treatment of atherosclerosis. See *In the Case of D. D. Dominey, Sr.*, decision of Appeals Council (Dec. 1, 1975), attached as Exhibit A to Friedrich's reply brief, filed November 28, 1984, in relation to a prior motion. A decision of the Appeals Council is the final step in the administrative review process and constitutes the final decision of the Secretary. 20 C.F.R. §§404.900, 422.210, *see Rubin v. Weinberger*, 524 F.2d 497 (7th Cir. 1975). Moreover, the Secretary concedes that from 1980 to 1982 the Secretary left the decision whether there was Medicare coverage of chelation therapy up to the intermediaries, carriers, and their individual medical staffs. See defendant's brief at p. 14.

In view of this history, promulgation of the instructions at issue in 1982 represented a change in the policy of the Secretary, as opposed to a mere clarification of an existing regulation. Thus, the chelation therapy instructions are substantive rather than interpretative and are subject to the notice and comment provisions of the A.P.A.

The notice and comment requirements were established to "curb bureaucratic actions taken without consultation and notice to persons affected." *American Academy of Pediatrics v. Heckler*, 561 F.Supp. 395, 398 (D.D.C. 1983). A substantive agency rule adopted without following the notice and comment procedures of the A.P.A. is not valid and enforceable. *Chrysler Corp. v. Brown*, 441 U.S. 281, 312-16 (1979); *State of Ohio, supra*, slip op. at 18-19.

In summary, the O.B.R.A. promulgated in 1986 and effective, in pertinent part, beginning January 1, 1987, does not apply to plaintiff's challenge to the chelation therapy in 1983. Moreover, the Secretary's chelation instructions are substantive, not interpretative, thus are invalid because they were not promulgated pursuant to the notice and public comment procedures of the A.P.A.

Due Process

The Fifth and Fourteenth Amendments protect citizens from the government's deprivation of life, liberty or property without due process of law. Due process entitles citizens to minimum procedural safeguards of notice and a fair hearing before their property may be taken. *Mathews v. Eldridge,* 424 U.S. 319 (1976). The due process clause protects a number of property interests. *Goldberg v. Kelly,* 397 U.S. 254 (1970) (continued welfare benefits); *Goss v. Lopez,* 419 U.S. 565 (1975) (public school attendance); *Bell v. Burson,* 402 U.S. 535 (1971) (drivers license); *Perry v. Sindermann,* 408 U.S. 593 (1972) (public employment).

In the case at bar, it must be determined if Friedrich has a property interest which the due process clause protects. If he has such a property interest, it must be determined what process is due.

In defining the property interest which the due process clause protects, the Supreme Court has stated:

> To have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it. He must have more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it.

Board of Regents v. Roth, 408 U.S. 564, 577 (1972). This legitimate claim of entitlement must be created and defined by an independent source such as state or federal law. *Id.*

Friedrich had a legitimate claim of entitlement to Part B Medicare program benefits. They were created by federal law. Each month Friedrich paid a fee to be covered under Part B. His interest in reimbursement under the Part B program is the type of property interest which the due process clause protects.

It must next be determined what process is due. The Supreme Court considers a number of factors in determining what procedural safeguards are protected by the due process clause, and in general requires that procedures "be tailored . . . to insure that [people] are given a meaningful opportunity to present their case." *Mathews*, 424 U.S. at 319.

Friedrich was not given a meaningful opportunity. The hearing officer, though permitting Friedrich to offer evidence that his chelation therapy was medically reasonable, did not actually consider this evidence. The hearing officer was bound by the chelation therapy instructions of the carrier's manual. As noted earlier, these instructions were invalid. A meaningful opportunity in this case requires that the hearing officer rule on Friedrich's chelation therapy claim without considering the instructions.

Due process also requires that the hearing officer be a detached and neutral decision maker. *Withrow v. Larkin*, 421 U.S. 35, 46 (1975), *Gibson v. Berryhill*, 411 U.S. 564, 579 (1973); *In re Muchison*, 349 U.S. 133, 136 (1955). The hearing officer in Friedrich's case was bound by the invalid chelation therapy instructions, thus was

not neutral and detached. Due process requires a hearing officer whose decision is not bound by the invalid instructions.

Summary

In causing Friedrich's chelation therapy claim to be denied on the basis of the carrier's manual instructions, the Secretary did not comply with the A.P.A. and violated Friedrich's right to due process, thus this case must be remanded for another hearing to determine if Friedrich's claim should be reimbursed under Part B of Medicare. The Secretary's chelation therapy instructions shall have no force and effect on the hearing officer's decision. The hearing officer shall only consider the evidence presented at the hearing.

IT IS SO ORDERED.

/s/ JACK B. STREEPY
Jack B. Streepy
United States Magistrate

FINDINGS OF FACT, CONCLUSIONS AND ORDER OF THE MEDICARE HEARING OFFICER

(April 25, 1984)

MEDICARE
NATIONWIDE MUTUAL INSURANCE COMPANY
MEDICARE OPERATIONS
P.O. Box 16781 • Columbus, Ohio 43215

April 25, 1984

Lawrence J. Miltner, Esq.
Seeley, Savidge & Aussem
800 Fidelity Building
1940 East Sixth Street
Cleveland, Ohio 44114

Dear Mr. Miltner:

Re: Michael Friedrich
HI# 273-07-1909-A
MH# 14025

Attached is the hearing decision on the above listed beneficiary, which was prepared after carefully reviewing all available evidence.

Sincerely,

/s/ FRANK B. CREWS
Hearing Officer
Medicare Hearings Division

FBC/ras

Attachment

MEDICARE	Date of Hearing	:	March 19, 1984
PART B	Case No.	:	MH# 14025
HEARING	Soc.Sec.Acct.No.	:	273-07-1909-A
	Beneficiary	:	Michael Friedrich

FACTS

This case before the Hearing Officer was held but under protest by Lawrence J. Miltner, attorney with Seeley, Savidge and Aussem, L.P.A., representing, Michael J. Friedrich, the Medicare beneficiary. On February 21, 1984, Mr. Miltner sent a letter to Frank B. Crews, Hearing Officer, appointed by the carrier to hear the case, and is quoted here in pertinent part:

> "Recently, Mr. Friedrich through the undersigned, who acts as his counsel in this matter, was advised that a "fair hearing" had been scheduled for March 19 at 3:00 at the Holiday Inn in Downtown Cleveland.
>
> In order for this hearing to be truly fair and to comply with the requirements of due process of law, Mr. Friedrich hereby makes the following requests:
>
> (1) That a hearing officer be assigned to hear Mr. Friedrich's appeal who is neither an employee of the carrier, Nationwide Insurance, nor is associated with any party nor interested either directly or indirectly in the outcome of the hearing.
>
> (2) That all persons whom the hearing officer has consulted or intends to consult, including carrier medical consultants and/or members of medical boards of review, be present at the time of the hearing to present their evidence.
>
> (3) That all documentary evidence which the hearing officer has considered or intends to consider in determining the rights of Mr.

Friedrich including but not limited to the Medicare Carrier's Manual and/or any instructions to carriers by the Secretary of the Department of Health & Human Services, be presented at the time of the hearing for examination by Mr. Friedrich and his counsel.

Mr. Friedrich maintains that, apart from consideration of the merits of this claim, the foregoing requests are the minimum requirements in order that Mr. Friedrich's right to be heard can be exercised fairly and in an impartial setting."

A reply was sent to Mr. Miltner on March 1, 1984 and is quoted here in pertinent part as follows:

"After reading your letter of February 21, 1984, it appears that you on behalf of your client, object to the carrier's designating me to be the hearing officer in this case.

In keeping with the intent of the Law, I refer you to Regulations Number 5 of the Code of Federal Regulations, Title 20, Chapter III Part 405—Subpart H, Review and Hearing under The Supplementary Medical Insurance Program. In your review of subpart H, please note the content of sections 405.823, 405.824 and 405.860 which reads in pertinent part as follows:

"§405.823 Hearing Officer.

Any hearing provided for in this subpart shall be conducted by a hearing officer designated by the appropriate official of the carrier.

"§405.824 Disqualification of Hearing Officer.

A hearing officer shall not conduct a hearing in any case in which he is prejudiced or partial with respect to any party, or if he has any interest in the matter before him. Notice of any objection with respect to the hearing officer who will conduct the hearing shall be made by the objecting party at his earliest opportunity. The

hearing officer shall consider such objection and shall at his discretion withdraw. If the hearing officer withdraws, the appropriate official of the carrier shall designate another hearing officer to conduct the hearing. If the hearing officer does not withdraw, the objecting party may present his objections to the carrier for consideration at any time prior to the issuance of a decision. The carrier shall review the request and take appropriate actions. The fact that a hearing officer is an employee of the carrier may not serve as prima facie cause of disqualification.

"§405.860 Authority of the Hearing Officer.

The hearing officer in exercising the authority to conduct a hearing under section 1842(b)(3)(C) of the Act is to comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as with policy statements, instructions and other guides issued by the Social Security Administration in accordance with the Secretary's agreement with the carrier's."

"Whomever the carrier designates to preside over this case will be required to recognize the Medicare Carriers Manual and consider section 45-20 ETHYLENEDIAMINE-TETRA-ACETIC ACID (EDTA) Chelation Therapy for Treatment of Atherosclerosis.

The use of EDTA as a chelating agent to treat atherosclerosis, arteriosclerosis, calcinosis, or similar generalized condition not listed by the FDA as an approved use is not covered. Any such use of EDTA is considered experimental.

"35-64 CHELATION THERAPY FOR TREATMENT OF ATHEROSCLEROSIS

Chelation therapy is the application of chelation techniques for the therapeutic or preventive effects of removing unwanted metal ions from the body. The application of chelation therapy using

ethylenediamine-tetra-acetic acid (EDTA) for the treatment and prevention of atherosclerosis is controversial. There is no widely accepted rationale to explain the beneficial effects attributed to this therapy. Its safety is questioned and its clinical effectiveness has never been established by well designed, controlled clinical trails. It is not widely accepted and practiced by American physicians. EDTA chelation therapy for atherosclerosis is considered experimental. For these reasons, EDTA chelation therapy for the treatment or prevention of atherosclerosis is not covered."

"Some practitioners refer to this therapy as chemoendarterectomy and may also show a diagnosis other than atherosclerosis, such as arteriosclerosis or calcinosis. Claims employing such variant terms should also be denied under this section.

The instructions and directions that would be considered by the hearing officer would also include section 2050.5(D) of the Medicare Carriers Manual which reads in pertinent part:

"2050.5 D. *Reasonableness and Necessity.*—Use of the drug or biological must be safe and effective and otherwise reasonable and necessary as specified in section 2303. Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this last requirement. Therefore, you may pay for the use of an FDA-approved drug or biological, if (1) it was injected on or after the date of the FDA's approval; (2) it is reasonable and necessary for the individual patient; and (3) all other applicable coverage requirements are met. Payment may not be made

> for particular uses of drugs that the FDA has expressly disapproved or that are designated as not covered in the Coverage Issues Appendix.
>
> Determinations as to whether an injection is reasonable and necessary for an individual patient should be made on the same basis as all other such determinations—with the advice of medical consultants and with reference to accepted standards of medical practice and the medical circumstances of the individual case. Below are guidelines identifying three categories with specific examples of situations in which injections would not be reasonable and necessary according to accepted standards of medical practice. . . .
>
> If an injection is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the entire charge (i.e., for both the drug and its administration) should be excluded from payment. . . ."
>
> It should be remembered that Title XVIII Health Insurance for the Aged and Disabled is an insurance program with coverage provisions, that also excludes from coverage certain items and services. This is true of all insurance plans or programs."

This case before the hearing officer is a result of an appeal by Lawrence J. Miltner, attorney with Seeley, Savidge and Aussem, a Legal Professional Association, representing Michael Friedrich, the Medicare beneficiary. Mr. Miltner objects to certain adverse determinations, on behalf of his client, under Medicare Part B as rendered by Nationwide Mutual Insurance Company, hereinafter referred to as the carrier. A review of the facts indicates

that Michael Friedrich was under care and attention of James P. Frackelton, M.D. who rendered professional services on the dates indicated below:

2-1-83	Consultation	$ 20.00	$20.00
	Injection-chelation Therapy	55.00	N/C
2-19-83	Consultation	20.00	20.00
	Injection-chelation Therapy	55.00	N/C
	Medication	70.00	N/C
3-4-83	Consultation	20.00	20.00
	Injection-chelation Therapy	55.00	N/C
	Medication	10.00	N/C
3-15-83	EKG	$ 30.00	$25.00
	Exercise tolerance Test (stress)	100.00	80.00
3-18-83	Consultation	20.00	20.00
	Injection-chelation Therapy	55.00	N/C
3-25-83	Medication	40.00	N/C
4-1-83	Consultation	20.00	20.00
	Injection-chelation Therapy	55.00	N/C
4-11-83	Medication	20.00	N/C
4-14-83	Consultation	20.00	20.00
	Injection-chelation Therapy	55.00	N/C
4-26-83	Medication	45.00	N/C
4-29-83	Consultation	20.00	13.60
	Injection-chelation Therapy	55.00	N/C

The amount billed for those services and the amount approved by the carrier are included here in. Laboratory procedures were performed by the King James Medical Lab. on February 2, 1983.

2-3-83	CBC	$11.99	10.55	9.00
	Metal Analysis—Urine		25.70	N/C
	SMAC	11.13	9.70	10.00
	Urinalysis		9.00	4.00
	T3	7.43	6.00	7.43
	Processing Fee		4.30	*

When Mr. Friedrich received the Explanation of Medicare Benefits denying coverage of the chelation therapy, he contacted the office of Seeley, Savidge and Aussem engaging the services of Jolan B. Vagi, who wrote a very lengthy letter to the carrier contesting their determination, denying coverage for chelation therapy. In this letter, she presented facts relative to Dr. Frackelton's position as a licensed physician practicing medicine in the state of Ohio, and that she felt that Dr. Frackelton treated Mr. Friedrich in a manner in which such treatments were reasonable and medically necessary. That only Dr. Frackelton is best familiarized with Mr. Friedrich's medical history, condition and needs. And that Dr. Frackelton knows after assessing the existing medical condition of his patient, what would constitute the best treatment for him. Therefore, Dr. Frackelton's judgement and decision to administer chelation therapy as reasonable necessary for his patient Mr. Friedrich is the best professional opinion in this particular matter and should be respected and not second guessed by payors. Other statements contained in

* This charge was incorporated into the other procedures.

the letter, report on the benefits EDTA chelation therapy listing thirteen different medical conditions which benefit from the use of this treatment.

In the reconsideration which followed, the carrier made a completely new and independent examination of the claim and the coverage provisions of the Medicare Program, and it was determined that chelation therapy may only be covered for the emergency treatment or control of specific conditions and that the claim submitted by Mr. Friedrich did not meet the requirements and they must again deny coverage of the services. Attorney Vagi was notified of the reconsideration determination and was advised if they were dissatisfied they could request a hearing. On July 5, 1983 Ms. Vagi submitted a letter to the Social Security Administration in Cleveland, Ohio restating much of the same information that was sent in a letter to Nationwide Mutual Insurance Company, the Medicare carrier. In addition there was a large number of documents that were sent with this letter relating to chelatin therapy, describing what chelation therapy is, in addition, to their opinion about how the American Law protects the patient's rights to choose a physician to treat an illness from among the physicians available to be selected. A number of cases in case law were submitted with the documents as evidence to support Dr. Frackelton's right to administer chelation therapy for his patient, Mr. Friedrich. Other supportive evidence consisted of reprints of the Journal Holistic Medicine, Volume 4, Number 1 spring/summer 1982:

CURRENT STATUS OF EDTA CHELATION THERAPY IN OCCLUSIVE ARTERIAL DISEASE

By Elmer M. Cranton, M.D.
James P. Frackelton, M.D.

Several other pamphlets or articles written by physicians including the paper titled:

OCULOCEREBROVASCULOMETRIC ANALYSIS

By E. W. McDonagh, D.O., F.A.C.G.P.
C. J. Rudolph, D.O., Ph.D.
E. Cheraskin, M.D., D.M.D.

KIDNEY EFFECTS OF ETHYLENE DIAMINETETRAACETIC ACID

By Elmer M. Cranton, M.D.

HISTORICAL BACKGROUND STATEMENT

By AAMP

EDTA CHELATION THERAPY III: TREATMENT OF PERIPHERAL ARTERIAL OCCLUSION, AN ALTERNATIVE TO AMPUTATION

By H. Richard Casdorph, M.D., Ph.D.
Charles H. Farr, M.D., Ph.D.

EDTA CHELATION THERAPY, EFFICACY IN ARTERIOSCLEROTIC HEART DISEASE

By H. Richard Casdorph, M.D., Ph.D.

AN OCULOCEREBROVASCULOMETRIC ANALYSIS OF THE IMPROVEMENT IN ARTERIAL STENOSIS FOLLOWING EDTA CHELATION THERAPY

By E. W. McDonagh, D.O.
C. J. Rudolph, D.O.
E. Cheraskin, M.D., D.M.D.

When the carrier received these documents they forwarded them and all other pertinent records to the Hearing Division, where the case was initially scheduled to be heard on November 9, 1983 in Middleburg Heights,

Ohio, however, Mr. Miltner contacted the hearing officer, who was assigned to the case at that time, to advise that Mrs. Vagi was no longer with Seeley, Savidge and Aussem and that he had taken over her case load which included the claim of Mr. Friedrich, And wished to postpone the hearing until after November 14, 1983. The case was then rescheduled for January 27, 1984 in Middleburg Heights, Ohio, however, on January 25, 1984 Mr. Miltner's office called and notified the hearing officer that he wished to postpone the hearing until a later date. On February 21, 1984 Mr. Miltner wrote to Frank B. Crews the hearing officer of the case objecting to him being the hearing officer, who was assigned to hear Mr. Friedrich's appeal; a copy of this letter was entered in evidence as a restatement of the attorney and Mr. Friedrich to the hearing officer, hearing the case, the reply also was introduced previously from the hearing officer to Mr. Miltner. The case was scheduled for and heard on March 19, 1989, in Cleveland, Ohio. Present at the hearing were Michael J. Friedrich, the Medicare beneficiary, Lawrence J. Miltner, attorney for Mr. Friedrich, James P. Frackelton, M.D., the treating physician and Warren DeLano, the administrative assistant to Dr. Frackelton.

ISSUE

Under the circumstances prevailing this case were the determinations of the carrier correct and in accordance with the provisions of Medicare Part B?

APPLICABLE LAW, REGULATIONS AND GUIDELINES

Nationwide Mutual Insurance Company, as a Medicare Part B carrier, is charged with many duties and responsibilities, not only from the statute itself, but also by the regulations issued pursuant to this statute. Congress, in drafting Title XVIII of the Social Security Act, made it clear that medical necessity must be demonstrated in order for payment to be made for any service under the Medicare program. Section 1862(a)(1) of the Act precludes any payment for any services which are not reasonable and necessary for the diagnosis and treatment of the patient. The exact wording of this section reads, in pertinent part, as follows:

> "Exclusions from Coverage
>
> Sec. 1862(a) Notwithstanding any other provisions of this title, no payment may be made under part A or part B for any expenses incurred for items or services—
>
> (1) which are not reasonable and necessary for the diagnosis or treatment of illness or to improve the functioning of a malformed body member;"

Further instructions on coverage and the processing of claims is found in the Medicare Carrier's Manual, a publication of the Health Care Financing Administration of the Department of Health and Human Services. Sections 35-64 and 45-20 of Chapter II are cited herein:

> "35-64 CHELATION THERAPY FOR TREATMENT OF ATHEROSCLEROSIS
>
> Chelation therapy is the application of chelation techniques for the therapeutic or preventative effects of removing unwanted metal ions from the body. The application of chelation therapy using

ethylenediamine-tetra-acetic acid (EDTA) for the treatment and prevention of atherosclerosis is controversial. There is no widely accepted rationale to explain the beneficial effects attributed to this therapy. Its safety is questioned and its clinical effectiveness has never been established by well designed, controlled clinical trials. It is not widely accepted and practiced by American physicians. EDTA chelation therapy for atherosclerosis is considered experimental. For these reasons, EDTA chelation therapy for the treatment or prevention of atherosclerosis is not covered.

Some practitioners refer to this therapy as chemoendarterectomy and may also show a diagnosis other than atherosclerosis, such as arteriosclerosis or calcinosis. Claims employing such variant terms should also be denied under this section.

45-20 ETHYLENEDIAMINE-TETRA-ACETIC (EDTA) CHELATION THERAPY FOR TREATMENT OF ATHEROSCLEROSIS

The use of EDTA as a chelating agent to treat atherosclerosis, calcinosis, or similar generalized condition not listed by the FDA as an approved use is not covered. Any such use of EDTA is considered experimental.

Section 2050.5 of the Medicare Carrier's Manual also has application in this case and is quoted here in pertinent part as follows:

"2050.5 *Drugs and Biological—General.*—Except for those drugs and biologicals which must be put directly into a item of durable medical equipment or prosthetic device, drugs and biologicals are covered; only if *all* of the following requirements are met; (a) they meet the definition of "drugs" or "biologicals"; (b) they are of the type that cannot be self-administered; (c) they are not excluded as immunizations; (d) they are reasonable and

necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice; and (e) they meet all the general requirements for coverage of items as "incident-to" a physician's services and (f) they have not been determined by the FDA to be less than effective.

Generally, prescription and nonprescription drugs and biologicals purchased by or dispensed to a patient are not covered.

A. *Definition of a Drug or Biological.*—Drugs and biologicals must be determined to meet the statutory definition as such. Under the statute, payment may be made for a drug or biological only where it is included, or approved for inclusion, in the latest official edition of the *United States Pharmacopoeia*, the *National Formulary*, or the *United States Homeopathic Pharmacopoeia*; or, except for those unfavorably evaluated in *AMA Drug Evaluations* (successor publication to *New Drugs*) or *Accepted Dental Therapeutics* (successor publication to *Accepted Dental Remedies*). Combination drugs are also included in the definition of drugs if the combination itself or all of the therapeutic ingredients of the combination are included, or approved for inclusion in any of the above drug compendia.

Where a drug is excluded from coverage because it is unfavorably evaluated in either the *AMA Drug Evaluations* or *Accepted Dental Therapeutics*, the exclusion applies to all uses for which the drug or biological was so unfavorably evaluated.

Drugs and biologicals are considered "approved for inclusion" in a compendium if approved under the established procedure by the professional organization responsible for revision of the compendium.

B. *Self-Administering of a Drug or Biological.*—Whether a drug or biological is of a type which cannot be self-administered is based on the usual method of administration of the *form* of that drug or biological as furnished by the physician. Thus, where a physician gives a patient pills or other oral medication, these are excluded from coverage since the form of the drug given to the patient is usually self-administered. Similarly, if a physician gives a patient an injection which is usually self-injected (thus far insulin is the only drug determined to fall in this category), this drug is excluded from coverage, unless administered to the patient in an emergency situation (e.g., diabetic coma). Where, however, a physician injects a drug is not usually self-injected, this drug is not subject to the self-administrable drug exclusion (regardless of whether the drug may also be available in oral form) since it is not self-administrable in the form in which it was furnished to the patient.

Whole blood is a biological which cannot be self-administered and is covered when furnished incident to a physician's services. Payment may also be made for blood fractions if all coverage requirements are satisfied.

C. *Immunizations.*—Vaccinations or inoculations are excluded as "immunizations" unless they are directly related to the treatment of an injury or direct exposure to a disease or condition, such as antirabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin sera, or immune globulin. In the absence of injury or direct exposure, preventive immunization (vaccination or inoculation) against such diseases as smallpox, polio, diphtheria, etc., *is not covered.* (Flu injections are administered as a preventive measure and are excluded from coverage without regard to a patient's particular susceptibility to influenza.) In cases where a vaccination or inoculation is excluded from coverage, the entire charge should be denied.

D. *Reasonableness and Necessity.*—Use of the drug or biological must be safe and effective and otherwise reasonable and necessary as specified in section 2303. Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this last requirement. Therefore, you may pay for the use of an FDA approved drug or biological, if (1) it was injected on or after the date of the FDA's approval; (2) it is reasonable and necessary for the individual patient; and (3) all other applicable coverage requirements are met. Payment may not be made for particular uses of drugs that the FDA has expressly disapproved or that are designated as not covered in the Coverage Issues Appendix.

If you have reason to question whether the FDA has approved a drug or biological for marketing, you should obtain satisfactory evidence of FDA's approval. Acceptable evidence includes a copy of the FDA's letter to the drug's manufacturer approving the new drug application (NDA); or listing of the drug or biological in the FDA's *Approved Drug Products* or *FDA Drug and Device Product Approvals;* or a copy of the manufacturer's package insert, approved by the FDA as part of the labeling of the drug, containing its recommended uses and dosage, as well as possible adverse reactions and recommended precautions in using it. When necessary, the Medicare regional office may be able to help in obtaining information.

Determinations as to whether an injection is reasonable and necessary for an individual patient should be made on the same basis as all other such determinations—with the advice of medical consultants and with reference to accepted standard of medical practice and the medical circumstances of the individual case. Below are guidelines identifying three categories with specific examples of situations in which injections would not be reasonable and necessary according to accepted standards of

medical practice. You should supplement the guidelines below with guidelines concerning appropriate use of specific injections in other situations. The guidelines should be used to screen out for denial claims in which use of the injection billed for would not be reasonable and necessary, and to screen out questionable cases for special review or further development. Sample or other types of review of drug treatment should be coordinated with PSRO review of drug treatment.

If an injection is determined not be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the entire charge (i.e., for both the drug and its administration) should be excluded from payment. In addition, in those situations where it comes to the carrier's attention (e.g., from a beneficiary contact) or otherwise becomes apparent that an individual physician is billing for other services (such as office visits) which were primarily for the purpose of administering a noncovered injection (i.e., an injection that is not reasonable and necessary for the diagnosis or treatment of an illness or injury), the charge for such services should also be excluded from payment.

Regulations number 5—Subpart H, Section 405.823 Title Hearing Officer any hearing provided for in this subpart shall be conducted by a hearing officer designated by the appropriate official of the carrier, section 405.824 Disqualification of hearing officer.

A hearing officer shall not conduct a hearing in any case in which he is prejudiced or partial with respect to any party, or if he has any interest in the matter before him. Notice of any objection with respect to the hearing officer who will conduct the hearing shall be made by the objecting party at his earliest opportunity. The hearing officer shall consider such objection and shall at his discretion withdraw. If the hearing officer withdraws, the appropriate official of

the carrier shall designate another hearing officer to conduct the hearing. If the hearing officer does not withdraw, the objecting party may present his objections to the carrier for consideration at any time prior to the issuance of a decision. The carrier shall review the request and take appropriate action. The fact that a hearing officer is an employee of the carrier may not serve as prima facie cause of disqualification.

§405.860 Authority of the Hearing Officer

The hearing officer in exercising the authority to conduct a hearing under section 1842(b)(3)(C) of the Act is to comply with all the provisions of Title XVIII of the Act and regulations issued thereunder, as well as with policy statements, instructions and other guides issued by the Social Security Administration in accordance with the Secretary's agreement with the carriers.

During the course of the hearing, Mr. Miltner began his opening statement, submitting as claimant's Exhibit A-I and are identified as follows:

Exhibit A— Copy of his letter dated February 21, 1984 addressed to Frank B. Crews which contains his objection to the hearing officer hearing the case

Exhibit B— Copy of the hearing officer's reply to Mr. Miltner stipulating the basis for his hearing the case, citing Section 405.824 Disqualification of Hearing Officer

Exhibit C— Contains the listing of the various laboratories procedures performed on Mr. Friedrich

Exhibit C1— Listing the dates on which chelation therapy was administered to Mr. Friedrich

Exhibit D— Journal of Holistic Medicine, Volume 6, Number 1, spring/summer 1984. FREE RADICAL PATHOLOGY IN AGE-ASSOCIATED DISEASES: TREATMENT WITH EDTA CHELATION, NUTRITION AND ANTIOXIDANTS written by E. M. Cranton, M.D. and J. P. Frankelton, M.D.

Exhibit E— APPENDIX XII prepared by R. Casdorph, M.D., Ph.D. "EDTA CHELATION THERAPY, EFFICACY IN ARTERIOSCLEROTIC HEART DISEASE" Journal of Holistic Medicine, Volume 3, Number 1 (spring/summer 1981)

Exhibit H— PROTOCOL FOR USE OF EDTA CHELATION THERAPY IN ARTERIOSCLEROSIS FOR MEMBERS OF THE AMERICAN ACADEMY OF MEDICAL PREVENTICS

Exhibit I— FOREWORD TO THE THIRTY-EIGHTH EDITION.

CONCLUSION

On April 3, 1984 Mr. Miltner wrote to the hearing officer restating his objections to having him as a hearing officer, this letter is quoted in pertinent part as follows:

> "This matter came on for hearing on March 16, 1984 on the objections of Michael Friedrich for denial of reimbursement for chelation therapy and related treatment.
>
> This letter is to reaffirm the objections of Mr. Friedrich to the hearing officer stated both prior to and and at the time of the hearing. Mr. Friedrich's objections include: An objection to the hearing officer's impartiality for the reason that by administrative regulation, the hearing officer is required to follow the Medicare Carrier's Manual. Therefore, even if the claimant submits substantial evidence showing that the treatment which he received was both reasonable and necessary for the treatment of his illness, the hearing officer will be required by regulation to follow the Medicare Carrier's Manual even if said Manual is at variance with the testimony before him.
>
> Mr. Friedrich also objects to the hearing for the reason that he was not confronted with the medical consultants who have given their opinions with respect to chelation therapy and upon which it is expected that the hearing officer will rely in rendering a decision in this case.
>
> This letter is intended as a final renewal of these objections and the objections made both before and at the hearing so that these objections may be given due consideration prior to the rendering of a final written decision by the hearing officer."

Although the evidence and testimony presented at this hearing was impressive and implies that the efficacy of chelation therapy as a viable alternative to

conventional treatment for coronary artery disease, this does not alter the instructions contained in the carrier's manual that EDTA chelation therapy for the treatment or prevention of atherosclerosis is not covered. The coverage determinations are part of the instructions and guidelines issued to the carriers by the Secretary of the Department of Health and Human Services or his delegate.

I, Frank B. Crews, as the hearing officer, who was assigned to hear this case am not prejudice or partial with respect to any party nor do I have any special interest in the matter before me. I have no reason to withdraw from the hearing. Further there is no need to contact medical consultants or any other party to determine the coverage of this case.

A person enrolled under the Supplemental Medical Insurance Program has the right to select the physician of his choice to provide medical services. However, the Health Care Financing Administration's position is clear and unambiguous in that no program payment can be made for the administration of chelation therapy. In addition, the services rendered in the form of office visits and consultations as they were identified on the request for payment were performed with the purpose of administering chelation therapy or to evaluate the results of chelation therapy. Section 2050.5 of the Medicare Carrier's Manual indicates when an injection is administered, that has been determined not reasonable and necessary for the diagnosis or treatment of an illness or injury, the entire charge, both for the drug and its administration, should be excluded from payment. In addition, when it becomes apparent that an individual physician is billing for other services (such as office visits) which were primarily for the purposes of

administering a noncovered injection (that is, an injection that is not reasonable and necessary for the diagnosis or treatment of an illness or injury), the charge for such services should also be excluded from payment. The diagnoses listed on the claims that were submitted for payment under Medicare Part B were the following CAD; By-pass surgery; and heart disease. The only approved uses of chelation therapy, when it may be covered is in the following situations:

(1) lead poisoning

(2) hypercalcemia—qualified use because of nephrotoxic potential, used only in *dire emergencies* when death from hyper-calcemic crisis is imminent.

The diagnoses for which Mr. Friedrich received chelation therapy were CAD, by-pass surgery and heart disease; those are not among those that may be covered. The Secretary of the Department of Health and Human Services' position is clear and unambiguous in that no Program payment can be made for the medical procedures in the present case.

It is the opinion of the hearing officer that the services in the present case can not be covered under Medicare Part B.

/s/ FRANK B. CREWS
Hearing Officer
Medicare Hearing Division

April 26, 1984

Columbus, Ohio

ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT DENYING PETITION FOR REHEARING

(Filed March 7, 1990)

No. 89-3236

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

MICHAEL J. FRIEDRICH,
Plaintiff-Appellee,

vs.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Defendant-Appellant.

ORDER

Before: MILBURN and GUY, *Circuit Judges;* and LIVELY, *Senior Circuit Judge.*

Upon receipt and consideration of a petition for rehearing filed herein by the Plaintiff-Appellee, the court concludes that the petition for rehearing raises no issues not fully considered by the court upon the original submission and decision of this appeal. The petition for rehearing identifies no issue of fact or law either misapprehended or overlooked by the panel. Accordingly, the petition for rehearing is denied.

ENTERED BY ORDER OF THE COURT

BY: /s/ LEONARD GREEN
Clerk